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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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August 2, 2018

Dr. Frederick P. Cerise
President and CEO
Parkland Health and Hospital System
5200 Harry Hines Boulevard
Dallas, TX 75235

Dear Dr. Cerise:

Thank you for appearing before the Subcommittee on Health on July 11, 2018, to testify at the hearing entitled "Opportunities to Improve the 340B Drug Pricing Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on August 16, 2018. Your responses should be mailed to Dan Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to dan.butler@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

1. One thing that has been consistently reported by the GAO, HHS OIG, as well as published studies in JAMA (Journal of the American Medical Association) and Health Affairs, is the lack of transparency in the 340B program. Increased reporting, of the right measures, would allow Congress to understand how the 340B program dollars are being used to meet the health care needs of vulnerable patients. I find it interesting that some, but not all, 340B hospitals continue to say that on the one hand "they already have extensive reporting" but on the other hand "adding reporting would be onerous". This is circular logic. Hospitals do have the infrastructure to report measures – as they have emphasized that they currently have extensive reporting--- but some seem less interested in working with Congress to make sure that the measures reported on help improve the program. I think that we have lost sight of the fact that this program is completely VOLUNTARY. No one is forcing any entity to participate, and those who do not want to improve transparency can also choose to not participate in the program. Why do you think that some hospitals continue to say they cannot report measures?

2. Currently, certain rural and cancer hospitals are unable to access 340B pricing for orphan drugs, even when they are not being used to treat rare conditions. H.R. 2889, the "Closing Loopholes for Orphan Drugs Act" amends the Public Health Service Act to revise the 340B Drug Pricing Program to discount orphan drugs that are not being used to treat rare conditions for all entities covered by the program.

    a. Can Parkland Hospital acquire orphan drugs at 340B discounted prices when they use these drugs for non-orphan diseases or conditions?

        i. If so, how does acquiring these drugs at 340B discounted prices help Parkland Hospital serve vulnerable and low-income patients?

    b. Do you think it makes sense that some 340B covered entities can access 340B pricing for orphan drugs that are not being used to treat rare conditions while other 340B covered entities cannot buy these medicines at 340B prices?

3. There are concerns that some drug manufacturers have claimed orphan status for a drug and then marketed it for more common conditions without having to provide a 340B discount to some covered entities even when the drug is used for these more common conditions. If this is indeed happening, do you think H.R. 2889 would limit manipulation of the orphan drug exclusion?

The Honorable Robert E. Latta

1. How do you know that your 340B savings are benefitting low income and uninsured patients, and what do you do to ensure that these patients can afford their prescriptions?

The Honorable Leonard Lance

1. How do you believe HRSA could more efficiently administer and oversee this program?

2. What actions do you take to ensure compliance with existing regulations and guidelines set forth by HRSA?

The Honorable H. Morgan Griffith

1. Since entering the 340B program, has your hospital acquired "child sites", and if so, what is the reasoning behind these purchases? What types of practices has your hospital-acquired?

The Honorable Gus M. Bilirakis

1. My colleague Dr. Burgess has a discussion draft that would amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits under the 340B drug discount program in accordance with generally accepted government auditing standards. I think this is a good idea and one that would help improve the audits HRSA performs moving forward.

    a. Is there evidence that indicates HRSA's audits have increased the integrity of the 340B program?

    b. How do you think HRSA could best assess noncompliance? How could they ensure compliance before closing an audit?

    c. Because HRSA's audits only review a small number of drugs purchased through the 340B program, is it possible that instances of noncompliance could be much larger than audits suggest?

The Honorable Billy Long

1. In instances where a covered entity passes on the 340B discount to the patient in an in-house pharmacy, why would they not provide that same discount at one of their contract pharmacies?

2. In what ways do you benefit from contract pharmacy arrangements, and how do they help you achieve your mission?

3. Finally, do you think HRSA should issue guidance on how to determine patient eligibility for drug discounts?

The Honorable Larry Bucshon

1. How do you calculate your 340B savings, and do you set aside these savings for specific programs and initiatives, or do they go into a general fund?

2. Are covered entities required to report their savings to HRSA, and if not, does HRSA keep track of 340B savings through some other mechanism?

3. Is HRSA tracking how 340B revenue is spent?

4. Is there evidence that indicates covered entities are using 340B revenue for the original intended purposes of the program?

5. How do you know that your 340B savings are benefitting low income and uninsured patients, and what do you do to ensure that these patients can afford their prescriptions?

6. Would you support legislation to track how 340B savings are spent, and do you have any ideas or recommendations on how that would work?

The Honorable Susan W. Brooks

1. Can you describe the types of comprehensive services that 340B covered entities provide that are not normally seen in non-340B hospitals?

2. In your opinion, what would be the best metric to determine an entity's commitment to serving low-income and uninsured individuals?

The Honorable Markwayne Mullin

1. During a July 2017 hearing before the O&I subcommittee, HRSA testified that the Agency has struggled to clarify some of the 340B program requirements since they lack explicit regulatory authority for most provisions of the 340B statute and that "[s]pecific legislative authority to conduct rule making for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight and management of the program. Specifically, regulatory authority would also allow HRSA to provide greater clarity and specificity of program requirements." Parkland Hospital uses the 340B program to serve a very high percentage of low income uninsured and Medicaid beneficiaries. Do you think that HRSA should have the authority to make sure that all covered entities are using the 340B program to help serve vulnerable and low-income patient populations?

    a. If so, do you think providing HRSA with the authority to prescribe regulations as necessary or appropriate to carry out the 340B program will help achieve this goal?

The Honorable Richard Hudson

1. Does your entity provide 340B patients with drug discounts? How do you assess a patient's ability to pay for their prescriptions?

2. What percentage of your patients receive free medicine from a patient assistance program that is offered by a biopharmaceutical company or other entity?

The Honorable Earl L. "Buddy" Carter

1. What level of charity care is your hospital providing, and how did you come up with that number?

2. Are child sites required to abide by the same HRSA obligations as the parent site?

The Honorable Frank Pallone, Jr.

1. The 340B program plays a critically important role in our health care system, and the countless hearings had in the Committee on this topic have reaffirmed that point on both sides of the aisle. However it is very important to make certain those dollars do, in fact, go towards expanding services as the statute dictates and that all covered entities are carrying out the 340B program with the people it is intended to serve at the center of any policy decision and in full and transparent compliance with the law.

    a. Dr. Cerise, can you explain the complexity of tracking savings from 340B discounted drugs? How does Parkland ensure these dollars go towards expanding services for vulnerable patients? Please provide the Committee with any relevant or illustrative documentation to that effect.

2. On June 1, HRSA issued a final rule delaying the implementation of the 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties regulation until July 1, 2019. In the final rule on the delay, HRSA notes that this delay will "allow a more deliberative process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking…HHS intends to engage in additional or alternative rulemaking on these issues, and believes it would be counterproductive to effectuate the final rule prior to issuance of additional or alternative rulemaking on these issues."

    a. Can you describe and provide some information on the impact of this final rule to your institution? How would having access to ceiling prices change how the program is administered?

3. As you know, the Medicare program has recently implemented a nearly 30 percent cut to 340B hospitals.

    a. Please describe the impact this change will have on your ability to care for patients.